

**§ 17.25 Exchange of witness lists, witness statements, and exhibits.**

(a) At least 30 days before the hearing, or by such other time as is specified by the presiding officer, the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.

(b)(1) If a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the presiding officer will exclude such evidence if he or she determines that the failure to comply with paragraph (a) of this section should result in its exclusion.

(2) Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists under paragraph (a) of this section, he or she must exclude from the party's hearing evidence the testimony of any witness whose name does not appear on the witness list.

(3) If the presiding officer finds that extraordinary circumstances existed, the presiding officer must then determine whether the admission of the testimony of any witness whose name does not appear on the witness lists exchanged under paragraph (a) of this section would cause substantial prejudice to the objecting party. If the presiding officer finds that there is not substantial prejudice, the evidence may be admitted. If the presiding officer finds that there is substantial prejudice, the presiding officer may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless a party objects within 5 days prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

**§ 17.27 Hearing subpoenas.**

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may, when authorized by law, request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 20 days before the date fixed for the hearing unless otherwise allowed by the presiding officer, upon a showing by the party of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed for service of a complaint in § 17.7.

(f) If a party or the individual to whom the subpoena is directed believes a subpoena to be unreasonable, oppressive, excessive in scope, or unduly burdensome, or if it wishes to raise any other objection or privilege recognized by law, the party or individual may file a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service. Such a filing will state the basis for the motion to quash. The presiding officer may quash or modify the subpoena or order it implemented, as justice may require.

**§ 17.28 Protective order.**

(a) A party or a prospective witness may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) When issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that

would be withheld from public disclosure under 21 CFR part 20. Such orders may include, but are not limited to, one or more of the following:

- (1) That the discovery not be had;
- (2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
- (3) That the discovery may be had only through a method of discovery provided for by this part other than that requested;
- (4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;
- (5) That the contents of discovery or evidence be sealed;
- (6) That the information not be disclosed to the public or be disclosed only in a designated way; or
- (7) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the presiding officer.

#### § 17.29 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in a United States District Court. A check for witness fees and mileage shall accompany the subpoena when served.

#### § 17.30 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act or event, and includes the last day of the period, unless either such day is a Saturday, Sunday, or Federal holiday, in which event the time includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and Federal holidays shall be excluded from the computation.

(c) When a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response.

#### § 17.31 Form, filing, and service of papers.

(a) *Form.* (1) Documents filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., “motion to quash subpoena”).

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Division of Dockets Management.

(b) *Service.* A party filing a document with the Division of Dockets Management under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party's last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

#### § 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.